REVIEW

District Diabetes Registers: More Trouble Than They're Worth?

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Many areas in the UK are developing district-based diabetic registers with the anticipation that this will facilitate the call and recall of patients for regular reviews and thereby improve their quality of care, as well as provide data for many other uses, such as local healthcare planning and epidemiological research. But there are a clutch of unanswered questions which need attention. The ethical issues surrounding the consent and confidentiality of data on individuals are not resolved. There are practical problems which impede the collection and maintenance of complex data sets, especially if they are to include biomedical fields, and as yet no cost-effectiveness research which informs this debate. The argument that district registers may be the best way to demonstrate comprehensive diabetes services must not override two important concerns: firstly, where should the responsibility lie for monitoring silently damaging chronic illnesses—with patients, practices or districts, or all three? Secondly, if district level registers do become the accepted tools, let us not ignore the missing data field—that the quality of diabetic care is dependent more on the patient–doctor relationship than we want to acknowledge, or measure, however efficient our system. We conclude by observing that rudimentary registers are arriving in many areas, but the question remains—will diabetes registers aid the delivery of a high quality service for diabetes across the primary/secondary care interface? Truthfully, it is just too early to tell, and perhaps too late to ask?

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Introduction

> The NHS Executive is not convinced that there is a case for *national* chronic disease registers. . . It is for health authorities to decide whether they wish to make the necessary investment to establish *district* population-based registers.[1]

Humans have a soft spot for sweetness and denial is never easy. So managing diabetes is not about 'telling' people what to do. It's more about sharing decisions,[2] motivating and negotiating ways to control unruly sugar levels and manage other risks. But what about those 'invisible' patients—who, for one reason or another, muddle through, unchecked—the non-attenders, the 'lost to follow up'? Should we be ticking them off against a district register?

There is no consensus. Many doctors in primary care feel that the practice-based register is sufficient in order to monitor the care of diabetes patients. If we conclude that retinal surveillance (by optometry or photography) is cost-effective[3–5] it may be necessary to hold demographic data, at least, at a district level. One of the authors[6] questioned the trend towards chronic disease registers 17 years ago because of the cost, fragmentation of services, and possible false illusion of 'quality' caused by such systems. Others, usually specialists or public health physicians, regard this as dangerous naivety typical of those who, at best, are concerned about ethics beyond practicality and have a rosy view of quality in primary care, or of others who, at worst, want to avoid costs without counting benefits. Advocates argue that the silent insidious nature of diabetes end-organ damage means that many patients, although they regard diabetes as a serious condition, seem often indifferent to the importance of monitoring the disease.[7] This is especially true for those within immigrant and poor socio-economic groups. The move to create district-based monitoring systems has the support of patients[8] who perceive doctors' opposition to registers and audit as attempts to conceal the 'bad apples'. It is claimed there is little, if any, concern among patients about data confidentiality.

The Remaining Obstacles

Despite the 'it's down to you' advice from the NHS Executive[1] in 1996, district disease registers, with diabetes

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as the pioneer condition, are popping up everywhere. At the last count 26 existed and 56 were in development (unpublished British Diabetic Association survey, 1996). Many have developed from hospital diabetes clinical information systems. With no central policy guidance, there is, inevitably, significant diversity. Local arrangements have determined their geographical remit. They may be located in Trust Diabetes Centres, in primary care audit groups or within health authorities. Although consensus is emerging, the 'guardianship' of data is still debated, as are the thorny issues of patient consent and confidentiality. There also remains a clutch of incompletely answered questions. Although the potential functions can be listed (Box 1), can we confidently say 'why' diabetes registers are being constructed? Are there clear objectives for them, which are agreed and supported at patient, practitioner and epidemiological levels? Are such objectives achievable? Secondly, will these objectives justify the costs?

Box 1. Potential functions of a district diabetic register

- individual clinical care—structured surveillance
- analysis of aggregated data at practice and district level for performance audit
- prompt or recall for retinal surveillance purposes – possibly by optometrist or by retinal photography
- local needs assessment
- research resource (epidemiological and intervention studies)
- teaching (case identification)
- aggregation for health policy planning at regional level

The drive to create diabetes registers has been led by policy,[9] guided by reports that the impact of Type 2 diabetes has been grossly underestimated[10] and supported by the success of practice-based registers.[11–14] Adding momentum, specialists and others see registers as a resource that can facilitate the organization of care across the primary/secondary care divide;[8,15] for audit groups in general practice, registers are a way of potentially monitoring the 'quality' (currently 'quantity') of diabetes care.[16,17] Health service researchers will look for trends in diabetes outcomes and public health physicians see them as an assessment tool for local health needs.[18] There are also ambitions that diabetes registers might serve as a call and recall list for diabetic retinopathy screening.

Viewed from a 'medical', 'research' or 'public health' perspective it seems perverse to question the development of such registers. Our intention here is not to impede any potential improvement of diabetes care but to draw attention to the ethical, economic and practical issues that need clarification.

There are three major obstacles that hinder the development of computerized databases for diabetes:

1. Unresolved issues surrounding patient consent and data confidentiality.
2. Problems of electronic system compatibility.
3. Lack of central policy guidance regarding district clinical information system development.

Other areas will also impede progress: general practices, who have sustained many existing databases but who have received little or no useful feedback, will sooner or later ask questions about data ownership; boundary problems between practices, clinics, hospitals and health authorities will occur, especially in a climate of competitive contracting. Funding arguments, slow progress towards unique NHS identifiers, and database standardization will add to the inevitable delay in establishing coherent district systems.

Consent and Data Confidentiality

Although many registers exist, the validity of the patient consent obtained therein is doubtful. For consent to be informed, a process clearly stipulated in EL (96) 72,[1] 'patients should be made aware of the existence and the purpose of a register'. There are concerns that information held under current arrangements may not be legitimately used.[19] The General Medical Council guidelines[20] state that personal clinical information is confidential. Third parties are not allowed access unless the data is fully anonymized. Current guidance by the General Medical Council, the Data Protection Act (1984), the NHS Executive[21,22] and the British Medical Association[21,23] all err towards opt-in rather than opt-out consent before details are added to a centralized database. But there are fears that the practical difficulties of adopting a strict opt-in approach may make it impossible to get registers to anywhere vaguely approaching comprehensive coverage. According to a survey,[8] patients are overwhelmingly supportive of diabetes monitoring by district registers and put the potential of 'improved care' above concerns of confidentiality.

Although the solutions to these issues are simple in principle, they are difficult to put into practice. Strong guardianship of the register is essential. A Data Ownership Group should be established to be accountable for the security of the database, and hold responsibility for data access and its purpose.[8] The General Practice Audit Committee in Wales,[24] for example, has similarly drafted a policy supporting the establishment of district diabetic registers, provided that:

- They are resourced and managed by the health authority.
- A Data Guardian Group is appointed to monitor the use and interpretation of the data, and the absolute

confidentiality of the patients who have given informed consent for their information to be entered.
- The Data Guardian Group is formed with representatives from:
  - each discipline/profession involved in providing services to patients with the condition;
  - the local general practice-based primary care audit group (or equivalent);
  - patients with the condition.

Secondly, patients must be asked whether they are willing for their diabetes data to be held on a district database and be informed about the security, future use of such data, consent expiry, and renewal arrangements. Explicit ground rules legitimize district registers.

Data Collection, Management, and Maintenance

Consent and security issues are not the only unresolved problems. Meticulous data management is critical to successful district registers and will require continuous investment in information technology and skilled staff. If we accept that local co-ordination of diabetes care, quality monitoring, and outcome measurement are the prime functions, it becomes essential to include all diabetic patients so that the data become truly population based. Relying on one source of information, e.g. aggregating general practice data[25] or integrating data from primary and secondary care[8] may not capture the true population prevalence of known diabetes.[26] Much of the existing software, especially in primary care, does not yet have the capability of collecting or transferring aggregated electronic data, so that integrating information from hospitals, practices, pharmacies and other sources on a regular basis, although theoretically attractive, is currently very difficult. Research in Tayside has demonstrated the advantage of electronic record linkage to achieve a comprehensive register[26] but can that exercise be sustained in a service context? It is doubtful. The fact that there is an agreed standardized diabetic dataset in the UK[27] but wide variability in the data collected only emphasizes the distance between what could be possible if there was a cohesive information management policy and what currently exists.

Costs versus Benefits

We expect that the obstacles of consent, confidentiality, and technical incompatibility will be overcome. The resulting realization that registers bring with them clinical and service responsibilities will no doubt trigger an economic appraisal, notably absent from the current literature. It could be argued that if a register were to only prevent one lower limb amputation per year it would more than cover the cost of a register manager, the minimum resource required to run a locality database. There are other costs of course, both obvious (data ownership group), hidden (software maintenance), and opportunities lost (monitoring other chronic conditions) so there is a need to do the sums here. Cost estimates for running a diabetic call and recall register vary and have been put somewhere between £30 000 to £60 000 per year for an average health authority population.[17] If call and recall services for retinopathy screening services follow, costs will rise.

Early work suggests that by improving the process of care (quantity and quality of diabetic monitoring) intermediate outcomes (blood pressure and glycosylated haemoglobin) are improved (R.J. Young, personal communication). On the other hand, cautionary voices warn against setting targets for primary care using standards for metabolic control such as glycosylated haemoglobin derived from secondary care data.[28] Community-based studies consistently report mean glycosylated haemoglobin levels of 10 %[28] yet published standards regard such levels as indicating poor or very poor control. We need to understand what is meant by good quality care. Idealistic parameters imposed on general practice by register-driven monitoring systems may do more harm than good, particularly if introduced without adequate resources. One thing is clear, if it turns out that registers really do have the potential to improve outcomes, the passive central policy of allowing unguided development will need attention.

How Else Can We Improve the Quality of Diabetes Care?

Many diabetologists, public health physicians, commissioners, patient groups, and general practitioners avidly support the concept of district-led diabetes monitoring. Given the simplicity of the argument, let us pool together all diabetic patients, collect data systematically over time so that, through quality development—by improving process we will improve outcomes—perhaps the relatively modest costs of establishing an electronic database will not deter this enthusiasm or dash the hopes that accurate longitudinal data will help measure the benefit of current, and future, investment. How else are outcomes to be judged? Five to ten years ago there should have been an opportunity to develop pilot registers, learn from the process and compare the benefits, but, as with the chance to evaluate fundholding, that time has gone it seems. What is clear, however, is that prompting systems, for individual practices or for patients from groups of practices, is effective.[11–14] Do we need more than this, at district levels?

Are Electronic Registers 'Toys for the Boys'?

Niggling doubts remain, however, particularly in primary care. Centralized data do not automatically translate into effective care: district-led monitoring requires a

committed efficient organization which can be difficult to achieve in times of reorganization. Recall systems often fail, people are in hospital, take holidays, change names and addresses with irritating regularity or ignore our well-intentioned invitations.[29] It remains to be shown that district registers influence those critical tasks of diabetes management—such as successfully negotiating lifestyle changes[30] and achieving concordance with therapy[31,32] at the individual level—however accurate the database.

There are those who perceive electronic registers as 'toys for the boys', dependent on 'women's' work to keep them ever neat and tidy, but that they somehow miss the point? The provision of audit reports about all diabetic patients in a practice does not guarantee care at the individual level.[28,33] The radical alternative is an ideal, to pass responsibility back to the patient for follow-up, abandon call and recall systems and spend the time providing information and negotiating lifestyle changes: a patient driven self-management plan. Then, it might be argued that only a very small proportion of patients, who do not or cannot attend, need supervision: a carer or relative could adopt this responsibility, and the practice-based register can provide a safety net. Performance data would be dependent on occasional surveys rather than continuous collection. Clinicians would focus on clinical competencies. The central register would be dead and the ethical issues transparent.

Where Does this Leave the 'District Diabetes Register'?

Proposing patient power-with-responsibility is not a popular viewpoint. Patients want registers. Most diabetes specialists and the patients' organizations wish to see registers develop and public health physicians are not standing in their way. If we are talking about an annual letter inviting individuals for an annual review (including the retina), we need only the name and address. If we are thinking about performance feedback and outcomes research we need more agreement and organization than we now have within our grasp. The argument that district registers may be the best way to demonstrate comprehensive diabetes services must not override two important concerns: firstly, where should the responsibility lie for monitoring silently damaging chronic illnesses—with patients, practices or districts, or all three? Secondly, if district level registers do become the accepted tools, let us not ignore the missing data field, i.e. that the quality of diabetic care is dependent more on the patient–doctor relationship than we want to acknowledge, or measure, however efficient our system. We conclude by observing that rudimentary registers are arriving in many areas, but the question remains: will diabetes registers aid the delivery of a high quality service for diabetes across the primary/secondary care interface? Truthfully, it is just too early to tell and perhaps too late to ask?

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